Claims

1. A process for micronization of a pharmaceutically active agent comprising (a) suspending the pharmaceutically active agent in a propellant or in a compressed gas, (b) processing this suspension by high pressure homogenization, and (c) obtaining dry powder upon depressurization.

2. A process for microninization of a pharmaceutically active agent comprising (a) suspending the pharmaceutically active agent in a propellant, (b) processing this suspension by high pressure homogenization, and (c) obtaining a suspension of the micronized pharmaceutically active agent in a propellant.

3. The process according to claim 1 or 2 wherein the pharmaceutically active agent micronized by said process has an average particle size between about 0.1 and about 7.0 micrometers.

4. The process according to any preceding claim wherein the pharmaceutically active agent micronized by said process has an average particle size of from about 0.5 to about 5.0 micrometers.

5. The process according to any preceding claim wherein the suspension formed by the pharmaceutically active agent and the compressed gas or propellant comprises one or more pharmaceutically acceptable excipient.

6. The process according to any preceding claim wherein the pharmaceutically active agent is poorly soluble in water and/or chemically or thermally unstable.

7. The process according to any preceding claim wherein the pharmaceutically active agent is chosen from at least one of pimecrolimus (33-Epichloro-33-desoxy-ascomycin), 5-[(R)-2-(5,6-diethyl-indan-2-ylamino)-1-hydroxy-ethyl]-8-hydroxy-(1H)-quinolin-2-one, 3-methylthiophene-2-carboxylic acid (6S,9R,10S,11S,13S,16R,17R)-9-chloro-6-fluoro-11-hydroxy-17-methoxycarbonyl-10,13,16-trimethyl-3-oxo-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta-[α]phenanthren-17-yl ester, N-benzoylstaurosporine, oxcarbazepine, carbamazepine, 1-(2,6-Difluoro-

benzyl)-1H-[1,2,3]triazole-4-carboxylic acid amide, cox-2 inhibitors, pyrimidylalaminobenzamides, camptothecin derivatives , proteins, peptides, vitamins, steroids, bronchodilators.

8. The process according to any preceding claim wherein the compressed gas is chosen from at least one of carbon dioxide, nitrogen, dimethyl ether, ethane, propane and butane.

9. The process according to any preceding claim wherein the compressed gas is an HFA propellant qualified for human use.

10. The process according to any preceding claim wherein the compressed gas is chosen from at least one of HFA134a and HFA227.

11. The process according to claim 5 wherein the pharmaceutically active excipient is chosen from at least one of surfactant, carrier and lubricant.

12. The process according to claim 11 wherein the surfactant is chosen from at least one of acetylated monoglycerids, perfluorocarboxilic acid, polyethylene glycol (PEG) sterol esters, polyethylene oxide sorbitan fatty acid esters, sorbitan esters, sorbitan mono laureate, sorbitan mono oleate, sorbitan tri oleate, sorbitan mono palmitate, propylene glycol and oleic acid.

13. The process according to any preceding claim wherein the suspension of the pharmaceutically active agent in a propellant or compressed gas is processed by homogenization using static geometries.

14. The process according to any preceding claim wherein the suspension of the pharmaceutically active agent in a propellant or compressed gas is processed by homogenization using a dynamic valve.

15. The process according to any preceding claim wherein the suspension of the pharmaceutically active agent and the compressed gas or propellant is formed in a

first stirred vessel and stored in a second stirred vessel after the micronization process.

16. Micronized pharmaceutically active agent obtained by the process of any preceding claim.

17. A pharmaceutical composition comprising micronized pharmaceutically active agent obtained by the process of claim 16 and pharmaceutically acceptable excipients.

18. A package comprising a composition according to claim 17 and instructions to use.

19. A process according to any one of claims 1 to 15 wherein said micronized pharmaceutically active agent is prepared in situ in an inhalation device.

20. Use of micronized pharmaceutically active agent obtained by the process of claims 1 to 15 in inhalation formulations.

21. Use of micronized pharmaceutically active agent obtained by the process of any one of claims 1 to 15 in parenteral formulations.

22. An apparatus for micronization of a pharmaceutically active agent comprising
two stirred pressure vessels,
a high pressure homogenizier,
a fluid conduit interconnecting the stirred pressure vessels and the high pressure homogenizer.